Decision of Technical Board of Appeal 3.3.2 dated 30 September 1996

T 958/94 - 3.3.2

(Translation)

Composition of the board:

Chairman: P. A. M. Lançon

Members: C. Germinario

J. H. Van Moer

U. Oswald

W. Moser

Applicant/Appellant: Thérapeutiques substitutives

Headword: Anti-tumoral agent/THERAPEUTIQUES SUBSTITUTIVES

Article: 167(2)(a), 54(5) EPC

Rule: 67 EPC

Keyword: "Reservations - substantive equivalence of a claim directed to the use of a substance for the manufacture of a medicament and a claim directed to a process for the manufacture of the medicament using the same substance (yes)" - "Refund of fee for appeal (no)"

Headnote

A European patent may be granted with claims directed to the use of a substance or composition for the manufacture of a medicament for a specified new and inventive therapeutic application (G 5/83). Such use may be claimed in the form either of the application (or use) of a substance or composition for the manufacture of a medicament or of a process (or method) to manufacture a medicament characterised in the use of said

substance.

Summary of facts and submissions

I. Patent application No. 91 904 092.3, published as international publication No. WO-A-91/12 011, was refused by the examining division on the grounds that claim 1 for the contracting states Greece and Spain lacked novelty.

II. The application comprises a first set of four claims for all contracting states other than Greece and Spain, and a second set of four claims for Greece and Spain filed under Article 167(2)(a) EPC.

Independent claim 1 in the first set of claims is worded as follows:
"Use of a dextran derivative consisting of a polysaccharide chain substituted with carboxymethyl and carboxymethylbenzylamide sulphonate groups, said derivative being designated by the general formula ($D_XCM_YBS_Z$), wherein

X represents the average number of unsubstituted saccharide units per 100 saccharide units,

Y represents the average number of carboxymethyl groups per 100 saccharide units,

Z represents the average number of carboxymethylbenzylamide sulphonate groups per 100 saccharide units,

and X is equal to or lower than 50, Y is between 10 and 90, and Z is between 15 and 35,

to manufacture an agent for inhibiting the growth of tumor cells."

The subject-matter of claims 2 and 3 of the first set of claims is a dextran derivative *per se* with a more precise general formula than that in claim 1. The subject-matter of claim 4 of the first set of claims is a medicament comprising a dextran derivative as defined in claims 2

or 3.

The main claim for Greece and Spain reads as follows:

"Process for the manufacture of an agent for inhibiting the growth of tumor cells, characterised in the use, as an essential constituent of said agent, of a dextran derivative consisting of a polysaccharide chain substituted with carboxymethyl and carboxymethylbenzylamide sulphonate groups, said derivative being designated by the general formula ($D_XCM_YBS_Z$), wherein

X represents the average number of unsubstituted saccharide units per 100 saccharide units,

Y represents the average number of carboxymethyl groups per 100 saccharide units,

Z represents the average number of carboxymethylbenzylamide sulphonate groups per 100 saccharide units,

and X is equal to or lower than 50, Y is between 10 and 90, and Z is between 15 and 35."

The subject-matter of claims 2 to 4 is the conversion into a process of that of claims 2 to 4 in the first set of claims.

III. The decision refusing the application for lack of novelty is based on prior-art document FR-A-2 555 589.

This document describes dextran derivatives as defined in the refused application, their use as a medicament (especially as anticoagulant and anti-inflammatory agents and blood plasma substitutes) and a process for manufacturing the medicament.

The accepted difference between the prior-art document and the claimed invention lies in the therapeutic application of the medicament: to inhibit the growth of tumour cells.

After acknowledging that the subject-matter of claim 1 of the first set of claims, drafted in accordance with decision G 5/83 to protect the second medical indication of a medicament, was novel and inventive, the examining division refused the claims for Greece and Spain on the grounds that because they were directed to a process rather than an application or use they were not in the "second medical indication" form stipulated by the Enlarged Board of Appeal.

The examining division held that the novelty of "the use of a substance for the manaufacture of a medicament" was linked to formal requirements and that given the order of decision G 5/83 only **use** claims - not **process** ones - fulfilled those requirements.

IV. The appellant (applicant) filed an appeal against that decision.

The arguments submitted in the statement of grounds for appeal may be summarised as follows:

The Guidelines for Examination in the EPO (Part C, Chapter III, 4.9) acknowledge that a claim directed to the application or use of a substance to achieve a technical effect is equivalent to a claim directed to the process for achieving the same technical effect using the same substance. The logical inference is that application and process claims are also equivalent in the area of second medical indication.

This equivalence is also acknowledged by the Enlarged Board of Appeal, in points 11 and 21 of decision G 5/83.

Said decision makes no recommendation about how to formulate a claim for a second medical indication and has therefore been misinterpreted by the examining division.

The appellant also argues that two procedural violations justify a refund of the fee for appeal. First, the examining division has not complied with Rule 68(2) EPC, because its decision refusing the application was not sufficiently reasoned. Second, the application was refused on the basis of arguments not communicated to the applicant beforehand (Article 113(1)

EPC).

V. By communication of 19 January 1996, the board pointed out that the reservation under Article 167(2)(a) EPC did not affect the protection conferred by a European patent in so far as it involved a process of manufacture or use of a chemical product or a process of manufacture or use of a pharmaceutical or food product. It followed that said reservation did not appear to affect the use as per claim 1 for all contracting states other than Greece and Spain.

In reply to the questions raised, the appellant argued that in Spain at least there was uncertainty as to the validity of patents with use claims, and filed two auxiliary requests, the first being a "process of use" claim, the second a single set of claims for all the contracting states.

The appellant asks that the decision to refuse the application be set aside, that a patent be granted in the form refused by the examining division or as per one of the auxiliary requests, and that the fee for appeal be refunded.

Reasons for the decision

1. The appeal is admissible.

2. The claims filed in response to the communication under Rule 51(4) EPC for the contracting states Spain and Greece (the second set of claims) fulfil the requirements of Article 123(2) EPC; the manufacturing process claimed is described on pages 3 to 8 of the application as filed.

3.1 The claims for all the designated contracting states other than Spain and Greece (the first set of claims) read as follows:

"Use of a dextran derivative ... to manufacture an agent for inhibiting the growth of tumor cells".

The novelty of the subject-matter of the first set of claims was evaluated against document FR-A-2 555 589 as the closest prior art.

That document describes dextran derivatives as defined in claim 1 of the first set of claims, a process for their manufacture, and their medicinal use in particular as anticoagulant and anti-inflammatory agents and blood plasma substitutes.

It does not however disclose the use of dextran derivatives as an agent for inhibiting the growth of tumour cells.

In accordance with the reasons and order of each of the decisions G 1/83 (OJ EPO, 1985, 60), G 5/83 (OJ EPO, 1985, 64) and G 6/83 (OJ EPO, 1985, 67), the board therefore acknowledges that the subject-matter of the first set of claims is novel because of the medicament's new therapeutic application.

3.2 As regards the novelty of the subject-matter of the claims for Spain and Greece reading as follows:

"**Process for the manufacture of an agent for inhibiting the growth of tumor cells, characterised in the use, as an essential constituent of said agent, of a dextran derivative ...** ",

the examining division took the view that the new therapeutic application of the dextran derivatives, which had enabled it to regard the subject-matter of the first set of claims as novel, could not render novel the process for the medicament's manufacture, because a claim of that type did not meet the formal requirements laid down in the above decisions.

3.3 The board notes that Enlarged Board decisions G 1/83, G 5/83 and G 6/83 make no mention of requirements of form or category governing claims directed to a medicament's second therapeutic indication.

For the board, the French wording "revendications ayant pour objet" used in decision G 6/83

refers not to the formal aspect of the category of a claim but rather to its substance, ie the definition of the claimed invention in terms of its essential features.

Parallel decisions G 1/83 and G 5/83 in German and English use the words "Patentansprüche gerichtet auf" and "claims directed to" rather than "Gegenstand" or "subject-matter", which also shows that the determining factor is not the wording or category chosen for the claim but its substance, namely the technical feature which forms the essence of the invention claimed (use of the substance in question).

3.4 This interpretation is confirmed by the reasons for decisions G 1/83, G 5/83 and G 6/83.

First, in point 11 of decision G 5/83 (first paragraph) the Enlarged Board held that an invention relating to an activity could be claimed either as the application or use of a thing for a stated purpose (eg to achieve a technical result) or as a method or process to achieve the same result using the same thing, depending on the applicant's preference. Either type of claim also involved a sequence of steps giving rise to the final effect. In terms of use, therefore, there was no difference of substance.

This general rule also applies in the field of therapy. There is no discernible substantive difference between a claim for the use of a substance or composition for the treatment of the human or animal body by therapy and a claim directed to a method of treatment of the human or animal body by therapy. The sole difference is in the wording, as was emphasised by the Enlarged Board in point 13 of decision G 5/83.

This is why a substance's second therapeutic application cannot be protected in the form of the substance's direct use in a method of treatment by therapy (excluded from patentability under Article 52(4) EPC), but only in the form of a claim directed to the preliminary production (manufacture) of a medicament intended for the new application.

Manufacturing a medicament does indeed involve a sequence of common and obligatory steps, irrespective of the form of the claims which circumscribe its manufacture, and whether the claims are for the "application of a substance to obtain a medicament intended for a new

therapeutic use" or for a "process to obtain a medicament intended for the new application, characterised in that the substance is used". As pointed out in the second paragraph of point 11 of decision G 5/83, “in both cases the active substance or composition for therapy must be in a state capable of exerting its therapeutic activity and this necessarily means that the active material has been formulated and made up into doses".

Since, under decisions G 1/83, G 5/83 and G 6/83, both types of claim circumscribe in the same way the activity of formulating a medicament’s active substance, which constitutes the **process** for obtaining the medicament, no argument about the scope of protection conferred by use or method claims under Article 64(2) EPC can be invoked solely in order to draw an artificial substantive distinction between the two.

Therefore, and although the active substance per se, the medicament and the process for its manufacture were already known, the Enlarged Board in decisions G 1/83, G 5/83 and G 6/83 allowed a claim for preparing the medicament for the new therapeutic indication and directed to the substance’s use in manufacturing the medicament intended for that new therapeutic indication.

In the same conditions - ie where the active substance, the medicament and the process for its manufacture all lack novelty - it would therefore be unjustified to regard a claim of the type "method for manufacturing the medicament intended for the new therapeutic indication” as not patentable, given that a claim for the use of a substance to manufacture a medicament intended for a new therapeutic use and a claim for a method of manufacturing the medicament intended for the new use and characterised in that the same substance is used are substantively equivalent.

This would also clearly contradict point 21 of decision G 5/83, where the Enlarged Board says that “It seems justifiable ... to derive the novelty for the process which forms the subject-matter of the type of use claim now being considered from the new therapeutic use of the medicament, and this irrespective of whether any pharmaceutical use of the medicament was already known or not". In this passage the word "préparation" in French means the "activity” and thus the “process” of preparation, as is clear from the corresponding

terms “Herstellung” and “process” used in decisions G 1/83 and G 5/83 respectively.

In conclusion, the subject-matter of the claimed invention remains the same, whether defined according to the claims for all the designated states other than Greece and Spain or according to those for Greece and Spain. The two sets of claims are therefore substantively equivalent.

It follows that the subject-matter of claim 1 of the set of claims for the contracting states Greece and Spain according to the main request is novel for the same reasons as that of claim 1 of the set of claims for the other designated contracting states according to the main request.

With the present decision, the board confirms the direction already taken by decision T 893/90 of 22 July 1993 (not published in the Official Journal).

4. Since the claims for all the designated states other than Greece and Spain and those for Greece and Spain are substantively equivalent, the criteria which led the examining division to acknowledge that the first set of claims involved an inventive step also apply mutatis mutandis to the claims for Greece and Spain.

5. As regards the request that the fee for appeal be refunded, the board considers that the essential reasons for the decision to refuse the application had already been set out in the examining division’s communication dated 28 July 1993, which placed particular emphasis on the formulation of the claims.

The board also notes that the appellant’s arguments in reply to that communication were already, as regards the main passages, those set out in the statement of grounds for appeal.

The board therefore holds that the examining division did not use new arguments in its decision, and that Article 113(1) EPC has been observed.

The contested decision is also reasoned.

The board notes that the examining division did not regard the applicant's comments as relevant, and acknowledges that assessing the relevance of the arguments put forward is a matter for the instance which took the decision and that, under Article 97(1) EPC, such a decision concerns the application itself or the invention involved, and not the applicant's arguments.

The board therefore sees no procedural violations in the decision of the first-instance department, and no valid reason for refunding the fee for appeal under Rule 67 EPC.

Order

For these reasons it is decided that:

1. The contested decision is set aside.

2. The case is remitted to the department of first instance with the order to grant a patent with claims as per the main request.

3. The request that the fee for appeal be refunded is refused.